

Coordinating with APHIS on Overlap Agents and Toxins

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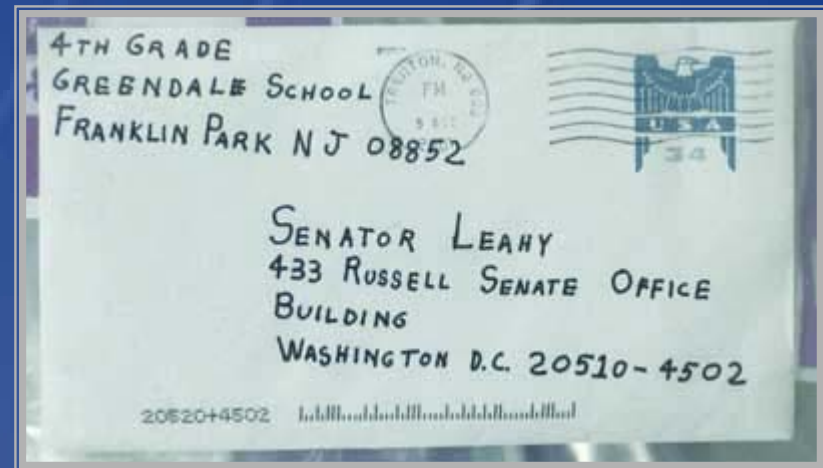
Antiterrorism and Effective Death Penalty Act of 1996

Sec. 511. Enhanced Penalties and Control of Biologic Agents
Public Law 104-132; April 24, 1996

The Secretary of HHS shall, through regulation:

- Maintain a list of biological agents that have the potential to pose a severe threat to public health and safety.
- Establish procedures for their transfer, including measures to ensure:
 - Proper training and appropriate skills to handle agents.
 - Proper laboratory facilities to contain and dispose of agents.

Post - September 11, 2001



Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Signed: June 12, 2002

- Significantly changed the regulatory authorities of HHS under Sec. 511 of the “Antiterrorism and Effective Death Penalty Act of 1996.”
- Granted comparable regulatory authorities to USDA for biological agents and toxins that present a severe threat to plant or animal health, or animal or plant products.
- Select agents and toxins subject to regulation by both agencies (“overlap”). Required coordination between USDA and HHS on “overlap” agents regulated by both agencies.

Types of Select Agents and Toxins

- **HHS-only Agents** (HHS has sole authority and responsibility to regulate)
 - Select agents and toxins that may affect public health and safety
- **USDA-only Agents** (USDA has sole authority and responsibility to regulate)
 - Select agents and toxins that may affect animal and plant health and animal and plant products
- **“Overlap Agents”**
 - Select agents and toxins subject to regulation by both agencies
- The Act provides for interagency coordination between the two departments regarding overlap select agents and toxins

Coordination with USDA / APHIS

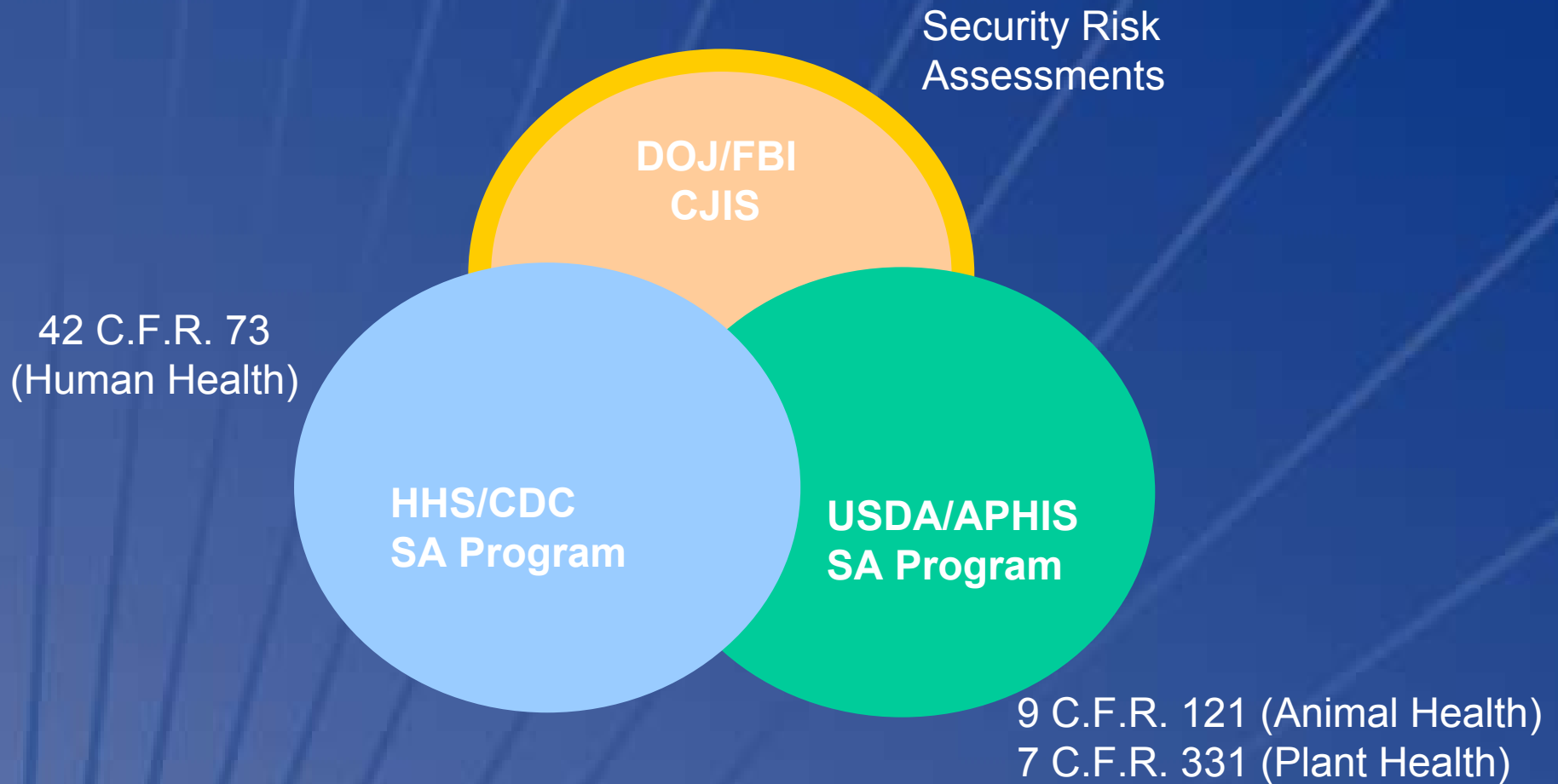
- If an entity has overlap agents, the entity may register with either CDC or APHIS
- Agencies will coordinate approvals of entities with overlap agents
 - Requires concurrence of other agency
- Registration package and other forms are the same for both agencies

Additional Efforts to Coordinate

- CDC and APHIS are working diligently to harmonize efforts and reduce the burden on entities, i.e., single registration system.
 - Entities should interface with only one agency for select agent issues
 - CDC/APHIS plan to provide increased communication and outreach to the regulated community so that regulatory requirements and means to accomplish compliance are transparent

- Inspections
 - APHIS has additional regulatory requirements for importation or interstate transfer of overlap and USDA-only agents (7 C.F.R. Part 330 and 9 C.F.R. Part 122)
 - Requires approval of permit application
 - May require inspection
 - For CDC-lead entities, APHIS is currently accepting CDC inspections to minimize burden on entities

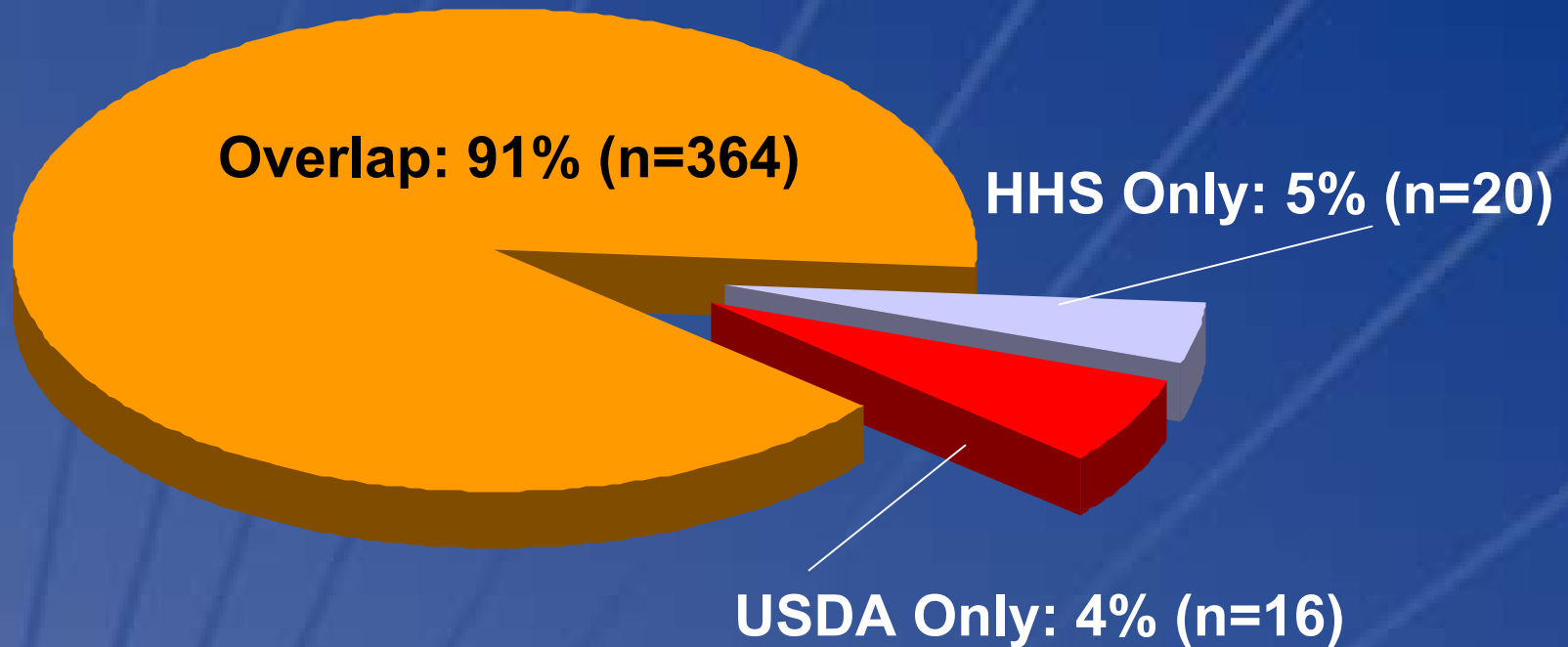
Federal Partners



Coordination with DOJ/FBI/CJIS

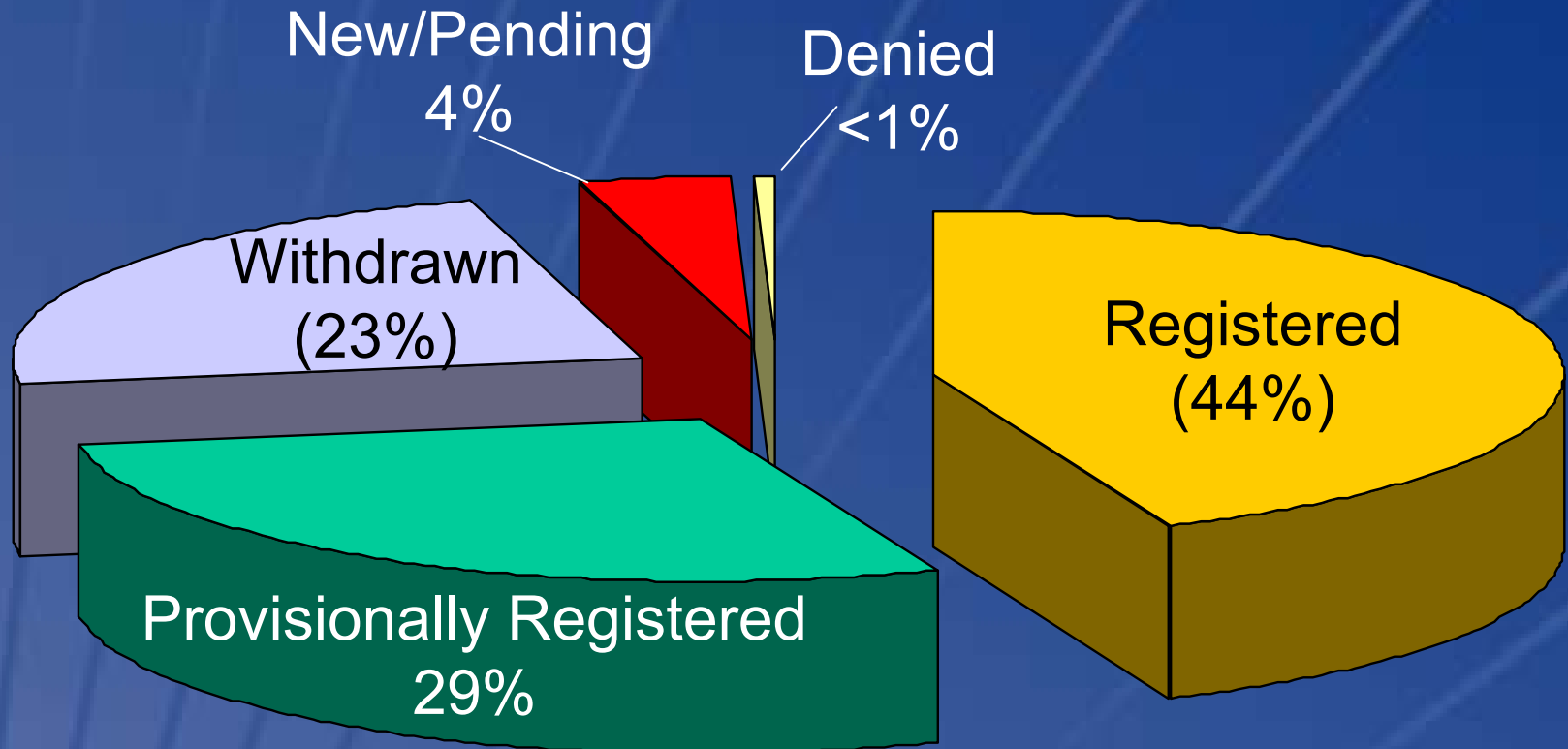
- All individuals needing access to select agents or toxins and owners of entities seeking to register must have a security risk assessment (database and fingerprint check) conducted by the Attorney General.
- The Attorney General has designated the Federal Bureau of Investigation (FBI), Criminal Justice Information Services Division (CJIS), to conduct the security risk assessments.
- CJIS sends results to lead agency (CDC or APHIS)
- Lead agency is responsible for reporting results back to the entity

Type of Select Agent or Toxin Registered under 42 C.F.R. 73, 9 C.F.R. 121 or 7 C.F.R. 331 (n=400)



Status of Entities Applying to CDC for Registration of Select Agents and Toxins

(N = 441 total received)



*Previously registered under 42 C.F.R. 72.6 = 56%

What's Next

- Work is ongoing between the partners to smooth out the operational wrinkles.
- Review comments received by both agencies on Interim Final Rule
- Publish Final Rule by late 2004

For More Information

- CDC Select Agent Program
 - Phone 404-498-2255
 - Fax 404-498-2265
 - E-mail lrsat@cdc.gov
 - Web site <http://www.cdc.gov/od/sap>
- USDA/APHIS
 - Phone 301-734-3277
 - Fax 301-734-3652
 - Web site <http://www.aphis.usda.gov/vs/ncie/bta.html>
- FBI
 - Phone 304-625-4900
 - Fax 304-625-5393
 - Web site <http://www.fbi.gov/hq/cjisd/cjis.htm>